

Union Calendar No. 565

110TH CONGRESS
2D SESSION

H. R. 6353

[Report No. 110–869, Part I]

To amend the Controlled Substances Act to address online pharmacies.

IN THE HOUSE OF REPRESENTATIVES

JUNE 24, 2008

Mr. STUPAK (for himself, Mr. SMITH of Texas, Mrs. BONO MACK, Mr. DANIEL E. LUNGREN of California, Mr. GALLEGLY, Mr. FEENEY, Mr. CHABOT, Mr. WALZ of Minnesota, and Mr. BOUCHER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

SEPTEMBER 23, 2008

Reported from the Committee on Committee on Energy and Commerce with
an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

SEPTEMBER 23, 2008

Additional sponsors: Mr. DAVIS of Illinois, Mr. LEVIN, Mrs. BACHMANN, Mrs. NAPOLITANO, and Mr. SOUDER

SEPTEMBER 23, 2008

Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

A BILL

To amend the Controlled Substances Act to address online pharmacies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Ryan Haight Online*
5 *Pharmacy Consumer Protection Act of 2008”.*

6 **SEC. 2. REQUIREMENT OF A VALID PRESCRIPTION FOR**
7 **CONTROLLED SUBSTANCES DISPENSED BY**
8 **MEANS OF THE INTERNET.**

9 *Section 309 of the Controlled Substances Act (21*
10 *U.S.C. 829) is amended by adding at the end the following:*

11 *“(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS*
12 *OF THE INTERNET.—*

13 *“(1) No controlled substance that is a prescrip-*
14 *tion drug as determined under the Federal Food,*
15 *Drug, and Cosmetic Act may be delivered, distributed,*
16 *or dispensed by means of the Internet without a valid*
17 *prescription.*

18 *“(2) As used in this subsection:*

19 *“(A) The term ‘valid prescription’ means a*
20 *prescription that is issued for a legitimate med-*

1 *ical purpose in the usual course of professional*
2 *practice by—*

3 *“(i) a practitioner who has conducted*
4 *at least 1 in-person medical evaluation of*
5 *the patient; or*

6 *“(ii) a covering practitioner.*

7 *“(B)(i) The term ‘in-person medical evalua-*
8 *tion’ means a medical evaluation that is con-*
9 *ducted with the patient in the physical presence*
10 *of the practitioner, without regard to whether*
11 *portions of the evaluation are conducted by other*
12 *health professionals.*

13 *“(ii) Nothing in clause (i) shall be con-*
14 *strued to imply that 1 in-person medical evalua-*
15 *tion demonstrates that a prescription has been*
16 *issued for a legitimate medical purpose within*
17 *the usual course of professional practice.*

18 *“(C) The term ‘covering practitioner’*
19 *means, with respect to a patient, a practitioner*
20 *who conducts a medical evaluation (other than*
21 *an in-person medical evaluation) at the request*
22 *of a practitioner who—*

23 *“(i) has conducted at least 1 in-person*
24 *medical evaluation of the patient or an*
25 *evaluation of the patient through the prac-*

1 *tice of telemedicine, within the previous 24*
 2 *months; and*

3 *“(ii) is temporarily unavailable to con-*
 4 *duct the evaluation of the patient.*

5 *“(3) Nothing in this subsection shall apply to—*

6 *“(A) the delivery, distribution, or dis-*
 7 *persing of a controlled substance by a practi-*
 8 *tioner engaged in the practice of telemedicine; or*

9 *“(B) the dispensing or selling of a con-*
 10 *trolled substance pursuant to practices as deter-*
 11 *mined by the Attorney General by regulation,*
 12 *which shall be consistent with effective controls*
 13 *against diversion.”.*

14 **SEC. 3. AMENDMENTS TO THE CONTROLLED SUBSTANCES**
 15 **ACT RELATING TO THE DELIVERY OF CON-**
 16 **TROLLED SUBSTANCES BY MEANS OF THE**
 17 **INTERNET.**

18 *(a) IN GENERAL.—Section 102 of the Controlled Sub-*
 19 *stances Act (21 U.S.C. 802) is amended by adding at the*
 20 *end the following:*

21 *“(50) The term ‘Internet’ means collectively the myr-*
 22 *iad of computer and telecommunications facilities, includ-*
 23 *ing equipment and operating software, which comprise the*
 24 *interconnected worldwide network of networks that employ*
 25 *the Transmission Control Protocol/Internet Protocol, or any*

1 predecessor or successor protocol to such protocol, to commu-
2 nicate information of all kinds by wire or radio.

3 “(51) The term ‘deliver, distribute, or dispense by
4 means of the Internet’ refers, respectively, to any delivery,
5 distribution, or dispensing of a controlled substance that
6 is caused or facilitated by means of the Internet.

7 “(52) The term ‘online pharmacy’—

8 “(A) means a person, entity, or Internet site,
9 whether in the United States or abroad, that know-
10 ingly or intentionally delivers, distributes, or dis-
11 penses, or offers or attempts to deliver, distribute, or
12 dispense, a controlled substance by means of the Inter-
13 net; and

14 “(B) does not include—

15 “(i) manufacturers or distributors registered
16 under subsection (a), (b), (d), or (e) of section
17 303 who do not dispense controlled substances to
18 an unregistered individual or entity;

19 “(ii) nonpharmacy practitioners who are
20 registered under section 303(f) and whose activi-
21 ties are authorized by that registration;

22 “(iii) any hospital or other medical facility
23 that is operated by an agency of the United
24 States (including the Armed Forces), provided

1 *such hospital or other facility is registered under*
2 *section 303(f);*

3 *“(iv) a health care facility owned or oper-*
4 *ated by an Indian tribe or tribal organization,*
5 *only to the extent such facility is carrying out a*
6 *contract or compact under the Indian Self-Deter-*
7 *mination and Education Assistance Act;*

8 *“(v) any agent or employee of any hospital*
9 *or facility referred to in clause (iii) or (iv), pro-*
10 *vided such agent or employee is lawfully acting*
11 *in the usual course of business or employment,*
12 *and within the scope of the official duties of such*
13 *agent or employee, with such hospital or facility,*
14 *and, with respect to agents or employees of*
15 *health care facilities specified in clause (iv), only*
16 *to the extent such individuals are furnishing*
17 *services pursuant to the contracts or compacts*
18 *described in such clause;*

19 *“(vi) mere advertisements that do not at-*
20 *tempt to facilitate an actual transaction involv-*
21 *ing a controlled substance;*

22 *“(vii) a person, entity, or Internet site that*
23 *is not in the United States and does not facili-*
24 *tate the delivery, distribution, or dispensing of a*

1 *controlled substance by means of the Internet to*
2 *any person in the United States;*

3 *“(viii) a pharmacy registered under section*
4 *303(f) whose dispensing of controlled substances*
5 *via the Internet consists solely of—*

6 *“(I) refilling prescriptions for con-*
7 *trolled substances in schedule III, IV, or V,*
8 *as defined in paragraph (55); or*

9 *“(II) filling new prescriptions for con-*
10 *trolled substances in schedule III, IV, or V,*
11 *as defined in paragraph (56); or*

12 *“(ix) any other persons for whom the Attor-*
13 *ney General and the Secretary have jointly, by*
14 *regulation, found it to be consistent with effective*
15 *controls against diversion and otherwise con-*
16 *sistent with the public health and safety to ex-*
17 *empt from the definition of an ‘online phar-*
18 *macy’.*

19 *“(53) The term ‘homepage’ means the opening or main*
20 *page or screen of the website of an online pharmacy that*
21 *is viewable on the Internet.*

22 *“(54) The term ‘practice of telemedicine’ means, for*
23 *purposes of this title, the practice of medicine in accordance*
24 *with applicable Federal and State laws by a practitioner*
25 *(other than a pharmacist) who is at a location remote from*

1 *the patient and is communicating with the patient, or*
2 *health care professional who is treating the patient, using*
3 *a telecommunications system referred to in section 1834(m)*
4 *of the Social Security Act, which practice—*

5 *“(A) is being conducted—*

6 *“(i) while the patient is being treated by,*
7 *and physically located in, a hospital or clinic*
8 *registered under section 303(f); and*

9 *“(ii) by a practitioner—*

10 *“(I) acting in the usual course of pro-*
11 *fessional practice;*

12 *“(II) acting in accordance with appli-*
13 *cable State law; and*

14 *“(III) registered under section 303(f)*
15 *in the State in which the patient is located,*
16 *unless the practitioner—*

17 *“(aa) is exempted from such reg-*
18 *istration in all States under section*
19 *302(d); or*

20 *“(bb) is—*

21 *“(AA) an employee or con-*
22 *tractor of the Department of Vet-*
23 *erans Affairs who is acting in the*
24 *scope of such employment or con-*
25 *tract; and*

1 “(BB) registered under sec-
2 tion 303(f) in any State or is uti-
3 lizing the registration of a hos-
4 pital or clinic operated by the De-
5 partment of Veterans Affairs reg-
6 istered under section 303(f);

7 “(B) is being conducted while the patient is
8 being treated by, and in the physical presence of, a
9 practitioner—

10 “(i) acting in the usual course of profes-
11 sional practice;

12 “(ii) acting in accordance with applicable
13 State law; and

14 “(iii) registered under section 303(f) in the
15 State in which the patient is located, unless the
16 practitioner—

17 “(I) is exempted from such registration
18 in all States under section 302(d); or

19 “(II) is—

20 “(aa) an employee or contractor
21 of the Department of Veterans Affairs
22 who is acting in the scope of such em-
23 ployment or contract; and

24 “(bb) registered under section
25 303(f) in any State or is using the reg-

1 *istration of a hospital or clinic oper-*
2 *ated by the Department of Veterans Af-*
3 *fairs registered under section 303(f);*

4 *“(C) is being conducted by a practitioner—*

5 *“(i) who is an employee or contractor of the*
6 *Indian Health Service, or is working for an In-*
7 *dian tribe or tribal organization under its con-*
8 *tract or compact with the Indian Health Service*
9 *under the Indian Self-Determination and Edu-*
10 *cation Assistance Act;*

11 *“(ii) acting within the scope of the employ-*
12 *ment, contract, or compact described in clause*
13 *(i); and*

14 *“(iii) who is designated as an Internet Eli-*
15 *gible Controlled Substances Provider by the Sec-*
16 *retary under section 311(g)(2);*

17 *“(D)(i) is being conducted during a public*
18 *health emergency declared by the Secretary under sec-*
19 *tion 319 of the Public Health Service Act; and*

20 *“(ii) involves patients located in such areas, and*
21 *such controlled substances, as the Secretary, with the*
22 *concurrence of the Attorney General, designates, pro-*
23 *vided that such designation shall not be subject to the*
24 *procedures prescribed by subchapter II of chapter 5 of*
25 *title 5, United States Code;*

1 “(E) is being conducted by a practitioner who
2 has obtained from the Attorney General a special reg-
3 istration under section 311(h);

4 “(F) is being conducted—

5 “(i) in a medical emergency situation—

6 “(I) that prevents the patient from
7 being in the physical presence of a practi-
8 tioner registered under section 303(f) who is
9 an employee or contractor of the Veterans
10 Health Administration acting in the usual
11 course of business and employment and
12 within the scope of the official duties or con-
13 tract of that employee or contractor;

14 “(II) that prevents the patient from
15 being physically present at a hospital or
16 clinic operated by the Department of Vet-
17 erans Affairs registered under section
18 303(f);

19 “(III) during which the primary care
20 practitioner of the patient or a practitioner
21 otherwise practicing telemedicine within the
22 meaning of this paragraph is unable to pro-
23 vide care or consultation; and

24 “(IV) that requires immediate inter-
25 vention by a health care practitioner using

1 *controlled substances to prevent what the*
2 *practitioner reasonably believes in good*
3 *faith will be imminent and serious clinical*
4 *consequences, such as further injury or*
5 *death; and*

6 *“(ii) by a practitioner that—*

7 *“(I) is an employee or contractor of the*
8 *Veterans Health Administration acting*
9 *within the scope of that employment or con-*
10 *tract;*

11 *“(II) is registered under section 303(f)*
12 *in any State or is utilizing the registration*
13 *of a hospital or clinic operated by the De-*
14 *partment of Veterans Affairs registered*
15 *under section 303(f); and*

16 *“(III) issues a controlled substance*
17 *prescription in this emergency context that*
18 *is limited to a maximum of a 5-day supply*
19 *which may not be extended or refilled; or*

20 *“(G) is being conducted under any other cir-*
21 *cumstances that the Attorney General and the Sec-*
22 *retary have jointly, by regulation, determined to be*
23 *consistent with effective controls against diversion*
24 *and otherwise consistent with the public health and*
25 *safety.*

1 “(55) *The term ‘refilling prescriptions for controlled*
2 *substances in schedule III, IV, or V’—*

3 “(A) *means the dispensing of a controlled sub-*
4 *stance in schedule III, IV, or V in accordance with*
5 *refill instructions issued by a practitioner as part of*
6 *a valid prescription that meets the requirements of*
7 *subsections (b) and (c) of section 309, as appropriate;*
8 *and*

9 “(B) *does not include the issuance of a new pre-*
10 *scription to an individual for a controlled substance*
11 *that individual was previously prescribed.*

12 “(56) *The term ‘filling new prescriptions for controlled*
13 *substances in schedule III, IV, or V’ means filling a pre-*
14 *scription for an individual for a controlled substance in*
15 *schedule III, IV, or V, if—*

16 “(A) *the pharmacy dispensing that prescription*
17 *has previously dispensed to the patient a controlled*
18 *substance other than by means of the Internet and*
19 *pursuant to the valid prescription of a practitioner*
20 *that meets the applicable requirements of subsections*
21 *(b) and (c) of section 309 (in this paragraph referred*
22 *to as the ‘original prescription’);*

23 “(B) *the pharmacy contacts the practitioner who*
24 *issued the original prescription at the request of that*
25 *individual to determine whether the practitioner will*

1 authorize the issuance of a new prescription for that
2 individual for the controlled substance described in
3 subparagraph (A); and

4 “(C) the practitioner, acting in the usual course
5 of professional practice, determines there is a legiti-
6 mate medical purpose for the issuance of the new pre-
7 scription.”.

8 (b) *REGISTRATION REQUIREMENTS*.—Section 303(f) of
9 the Controlled Substances Act (21 U.S.C. 823(f)) is amend-
10 ed in the matter preceding paragraph (1)—

11 (1) in the first sentence, by adding after “sched-
12 ule II, III, IV, or V” the following: “and shall modify
13 the registrations of pharmacies so registered to au-
14 thorize them to dispense controlled substances by
15 means of the Internet”; and

16 (2) in the second sentence, by striking “if he de-
17 termines that the issuance of such registration” and
18 inserting “or such modification of registration if the
19 Attorney General determines that the issuance of such
20 registration or modification”.

21 (c) *REPORTING REQUIREMENTS*.—Section 307(d) of
22 the Controlled Substances Act (21 U.S.C. 827(d)) is amend-
23 ed by—

24 (1) striking “(d) Every” and inserting “(d)(1)
25 Every”; and

1 (2) *adding at the end the following:*

2 “(2) *Each pharmacy with a modified registration*
 3 *under section 303(f) that authorizes the dispensing of con-*
 4 *trolled substances by means of the Internet shall report to*
 5 *the Attorney General the controlled substances it dispenses,*
 6 *in the amount specified, and in such time and manner as*
 7 *the Attorney General by regulation shall require, except that*
 8 *the Attorney General, under this paragraph, may not re-*
 9 *quire any pharmacy to report any information other than*
 10 *the total quantity of each controlled substance that the phar-*
 11 *macy has dispensed each month. For purposes of this para-*
 12 *graph, no reporting shall be required unless the pharmacy*
 13 *has met 1 of the following thresholds in the month for which*
 14 *the reporting is required:*

15 “(A) *100 or more prescriptions dispensed.*

16 “(B) *5,000 or more dosage units of all controlled*
 17 *substances combined.”.*

18 (d) *ONLINE PRESCRIPTION REQUIREMENTS.—*

19 (1) *IN GENERAL.—The Controlled Substances Act*
 20 *is amended by inserting after section 310 (21 U.S.C.*
 21 *830) the following:*

22 “*ADDITIONAL REQUIREMENTS RELATING TO ONLINE*
 23 *PHARMACIES AND TELEMEDICINE*

24 “*SEC. 311. (a) IN GENERAL.—An online pharmacy*
 25 *shall display in a visible and clear manner on its homepage*
 26 *a statement that it complies with the requirements of this*

1 *section with respect to the delivery or sale or offer for sale*
2 *of controlled substances and shall at all times display on*
3 *the homepage of its Internet site a declaration of compliance*
4 *in accordance with this section.*

5 “(b) *LICENSURE.—Each online pharmacy shall com-*
6 *ply with the requirements of State law concerning the licen-*
7 *sure of pharmacies in each State from which it, and in*
8 *each State to which it, delivers, distributes, or dispenses or*
9 *offers to deliver, distribute, or dispense controlled substances*
10 *by means of the Internet, pursuant to applicable licensure*
11 *requirements, as determined by each such State.*

12 “(c) *INTERNET PHARMACY SITE DISCLOSURE INFOR-*
13 *MATION.—Each online pharmacy shall post in a visible and*
14 *clear manner on the homepage of each Internet site it oper-*
15 *ates, or on a page directly linked thereto in which the*
16 *hyperlink is also visible and clear on the homepage, the fol-*
17 *lowing information for each pharmacy that delivers, dis-*
18 *tributes, or dispenses controlled substances pursuant to or-*
19 *ders made on, through, or on behalf of, that website:*

20 “(1) *The name and address of the pharmacy as*
21 *it appears on the pharmacy’s Drug Enforcement Ad-*
22 *ministration certificate of registration.*

23 “(2) *The pharmacy’s telephone number and*
24 *email address.*

1 “(3) *The name, professional degree, and States of*
2 *licensure of the pharmacist-in-charge, and a telephone*
3 *number at which the pharmacist-in-charge can be*
4 *contacted.*

5 “(4) *A list of the States in which the pharmacy*
6 *is licensed to dispense controlled substances.*

7 “(5) *A certification that the pharmacy is reg-*
8 *istered under this part to deliver, distribute, or dis-*
9 *pense by means of the Internet controlled substances.*

10 “(6) *The name, address, telephone number, pro-*
11 *fessional degree, and States of licensure of any practi-*
12 *tioner who has a contractual relationship to provide*
13 *medical evaluations or issue prescriptions for con-*
14 *trolled substances, through referrals from the website*
15 *or at the request of the owner or operator of the*
16 *website, or any employee or agent thereof.*

17 “(7) *The following statement, unless revised by*
18 *the Attorney General by regulation: ‘This online*
19 *pharmacy will only dispense a controlled substance to*
20 *a person who has a valid prescription issued for a le-*
21 *gitimate medical purpose based upon a medical rela-*
22 *tionship with a prescribing practitioner. This in-*
23 *cludes at least one prior in-person medical evaluation*
24 *or medical evaluation via telemedicine in accordance*
25 *with applicable requirements of section 309.’.*

1 “(d) NOTIFICATION.—

2 “(1) IN GENERAL.—*Thirty days prior to offering*
3 *a controlled substance for sale, delivery, distribution,*
4 *or dispensing, the online pharmacy shall notify the*
5 *Attorney General, in such form and manner as the*
6 *Attorney General shall determine, and the State*
7 *boards of pharmacy in any States in which the online*
8 *pharmacy offers to sell, deliver, distribute, or dispense*
9 *controlled substances.*

10 “(2) CONTENTS.—*The notification required*
11 *under paragraph (1) shall include—*

12 “(A) *the information required to be posted*
13 *on the online pharmacy’s Internet site under*
14 *subsection (c) and shall notify the Attorney Gen-*
15 *eral and the applicable State boards of phar-*
16 *macy, under penalty of perjury, that the infor-*
17 *mation disclosed on its Internet site under sub-*
18 *section (c) is true and accurate;*

19 “(B) *the online pharmacy’s Internet site ad-*
20 *dress and a certification that the online phar-*
21 *macy shall notify the Attorney General of any*
22 *change in the address at least 30 days in ad-*
23 *vance; and*

24 “(C) *the Drug Enforcement Administration*
25 *registration numbers of any pharmacies and*

1 *practitioners referred to in subsection (c), as ap-*
2 *plicable.*

3 “(3) *EXISTING ONLINE PHARMACIES.*—*An online*
4 *pharmacy that is already operational as of the effec-*
5 *tive date of this section, shall notify the Attorney*
6 *General and applicable State boards of pharmacy in*
7 *accordance with this subsection not later than 30*
8 *days after such date.*

9 “(e) *DECLARATION OF COMPLIANCE.*—*On and after*
10 *the date on which it makes the notification under subsection*
11 *(d), each online pharmacy shall display on the homepage*
12 *of its Internet site, in such form as the Attorney General*
13 *shall by regulation require, a declaration that it has made*
14 *such notification to the Attorney General.*

15 “(f) *REPORTS.*—*Any statement, declaration, notifica-*
16 *tion, or disclosure required under this section shall be con-*
17 *sidered a report required to be kept under this part.*

18 “(g) *NOTICE AND DESIGNATIONS CONCERNING INDIAN*
19 *TRIBES.*—

20 “(1) *IN GENERAL.*—*For purposes of sections*
21 *102(52) and 512(c)(6)(B), the Secretary shall notify*
22 *the Attorney General, at such times and in such man-*
23 *ner as the Secretary and the Attorney General deter-*
24 *mine appropriate, of the Indian tribes or tribal orga-*
25 *nizations with which the Secretary has contracted or*

1 *compacted under the Indian Self-Determination and*
2 *Education Assistance Act for the tribes or tribal orga-*
3 *nizations to provide pharmacy services.*

4 “(2) *DESIGNATIONS.*—

5 “(A) *IN GENERAL.*—*The Secretary may des-*
6 *ignate a practitioner described in subparagraph*
7 *(B) as an Internet Eligible Controlled Sub-*
8 *stances Provider. Such designations shall be*
9 *made only in cases where the Secretary has*
10 *found that there is a legitimate need for the*
11 *practitioner to be so designated because the pop-*
12 *ulation served by the practitioner is in a suffi-*
13 *ciently remote location that access to medical*
14 *services is limited.*

15 “(B) *PRACTITIONERS.*—*A practitioner de-*
16 *scribed in this subparagraph is a practitioner*
17 *who is an employee or contractor of the Indian*
18 *Health Service, or is working for an Indian tribe*
19 *or tribal organization under its contract or com-*
20 *pact under the Indian Self-Determination and*
21 *Education Assistance Act with the Indian*
22 *Health Service.*

23 “(h) *SPECIAL REGISTRATION FOR TELEMEDICINE.*—

24 “(1) *IN GENERAL.*—*The Attorney General may*
25 *issue to a practitioner a special registration to engage*

1 *in the practice of telemedicine for purposes of section*
2 *102(54)(E) if the practitioner, upon application for*
3 *such special registration—*

4 “(A) *demonstrates a legitimate need for the*
5 *special registration; and*

6 “(B) *is registered under section 303(f) in*
7 *the State in which the patient will be located*
8 *when receiving the telemedicine treatment, unless*
9 *the practitioner—*

10 “(i) *is exempted from such registration*
11 *in all States under section 302(d); or*

12 “(ii) *is an employee or contractor of*
13 *the Department of Veterans Affairs who is*
14 *acting in the scope of such employment or*
15 *contract and is registered under section*
16 *303(f) in any State or is utilizing the reg-*
17 *istration of a hospital or clinic operated by*
18 *the Department of Veterans Affairs reg-*
19 *istered under section 303(f).*

20 “(2) *REGULATIONS.—The Attorney General*
21 *shall, with the concurrence of the Secretary, promul-*
22 *gate regulations specifying the limited circumstances*
23 *in which a special registration under this subsection*
24 *may be issued and the procedures for obtaining such*
25 *a special registration.*

1 “(3) *DENIALS.—Proceedings to deny an applica-*
 2 *tion for registration under this subsection shall be*
 3 *conducted in accordance with section 304(c).*

4 “(i) *REPORTING OF TELEMEDICINE BY VHA DURING*
 5 *MEDICAL EMERGENCY SITUATIONS.—*

6 “(1) *IN GENERAL.—Any practitioner issuing a*
 7 *prescription for a controlled substance under the au-*
 8 *thorization to conduct telemedicine during a medical*
 9 *emergency situation described in section 102(54)(F)*
 10 *shall report to the Secretary of Veterans Affairs the*
 11 *authorization of that emergency prescription, in ac-*
 12 *cordance with such requirements as the Secretary of*
 13 *Veterans Affairs shall, by regulation, establish.*

14 “(2) *TO ATTORNEY GENERAL.—Not later than 30*
 15 *days after the date that a prescription described in*
 16 *subparagraph (A) is issued, the Secretary of Veterans*
 17 *Affairs shall report to the Attorney General the au-*
 18 *thorization of that emergency prescription.*

19 “(j) *CLARIFICATION CONCERNING PRESCRIPTION*
 20 *TRANSFERS.—Any transfer between pharmacies of infor-*
 21 *mation relating to a prescription for a controlled substance*
 22 *shall meet the applicable requirements under regulations*
 23 *promulgated by the Attorney General under this Act.”.*

24 “(2) *TECHNICAL AND CONFORMING AMEND-*
 25 *MENTS.—The table of contents for the Comprehensive*

1 *Drug Abuse Prevention and Control Act of 1970*
 2 *(Public Law 91–513; 84 Stat. 1236) is amended by*
 3 *inserting after the item relating to section 310 the fol-*
 4 *lowing:*

“Sec. 311. Additional requirements relating to online pharmacies and telemedi-
 cine.”.

5 *(e) OFFENSES INVOLVING CONTROLLED SUBSTANCES*
 6 *IN SCHEDULES III, IV, AND V.—Section 401(b) of the Con-*
 7 *trolled Substances Act (21 U.S.C. 841(b)) is amended—*

8 *(1) in paragraph (1)—*

9 *(A) in subparagraph (D), by striking “or in*
 10 *the case of any controlled substance in schedule*
 11 *III (other than gamma hydroxybutyric acid), or*
 12 *30 milligrams of flunitrazepam”;* and

13 *(B) by adding at the end the following:*

14 *“(E)(i) Except as provided in subparagraphs (C) and*
 15 *(D), in the case of any controlled substance in schedule III,*
 16 *such person shall be sentenced to a term of imprisonment*
 17 *of not more than 10 years and if death or serious bodily*
 18 *injury results from the use of such substance shall be sen-*
 19 *tenced to a term of imprisonment of not more than 15 years,*
 20 *a fine not to exceed the greater of that authorized in accord-*
 21 *ance with the provisions of title 18, United States Code,*
 22 *or \$500,000 if the defendant is an individual or \$2,500,000*
 23 *if the defendant is other than an individual, or both.*

1 “(ii) If any person commits such a violation after a
2 prior conviction for a felony drug offense has become final,
3 such person shall be sentenced to a term of imprisonment
4 of not more than 20 years and if death or serious bodily
5 injury results from the use of such substance shall be sen-
6 tenced to a term of imprisonment of not more than 30 years,
7 a fine not to exceed the greater of twice that authorized in
8 accordance with the provisions of title 18, United States
9 Code, or \$1,000,000 if the defendant is an individual or
10 \$5,000,000 if the defendant is other than an individual, or
11 both.

12 “(iii) Any sentence imposing a term of imprisonment
13 under this subparagraph shall, in the absence of such a
14 prior conviction, impose a term of supervised release of at
15 least 2 years in addition to such term of imprisonment and
16 shall, if there was such a prior conviction, impose a term
17 of supervised release of at least 4 years in addition to such
18 term of imprisonment.”;

19 (2) in paragraph (2)—

20 (A) by striking “3 years” and inserting “5
21 years”;

22 (B) by striking “6 years” and inserting “10
23 years”;

24 (C) by striking “after one or more prior
25 convictions” and all that follows through “have

1 *become final,” and inserting “after a prior con-*
 2 *viction for a felony drug offense has become*
 3 *final,”; and*

4 *(3) in paragraph (3)—*

5 *(A) by striking “2 years” and inserting “4*
 6 *years”;*

7 *(B) by striking “after one or more convic-*
 8 *tions” and all that follows through “have become*
 9 *final,” and inserting “after a prior conviction*
 10 *for a felony drug offense has become final,”; and*

11 *(C) by adding at the end the following “Any*
 12 *sentence imposing a term of imprisonment under*
 13 *this paragraph may, if there was a prior convic-*
 14 *tion, impose a term of supervised release of not*
 15 *more than 1 year, in addition to such term of*
 16 *imprisonment.”.*

17 *(f) OFFENSES INVOLVING DISPENSING OF CON-*
 18 *TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—*
 19 *Section 401 of the Controlled Substances Act (21 U.S.C.*
 20 *841) is amended by adding at the end the following:*

21 *“(h) OFFENSES INVOLVING DISPENSING OF CON-*
 22 *TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—*

23 *“(1) IN GENERAL.—It shall be unlawful for any*
 24 *person to knowingly or intentionally—*

1 “(A) deliver, distribute, or dispense a con-
2 trolled substance by means of the Internet, except
3 as authorized by this title; or

4 “(B) aid or abet (as such terms are used in
5 section 2 of title 18, United States Code) any ac-
6 tivity described in subparagraph (A) that is not
7 authorized by this title.

8 “(2) *EXAMPLES.*—*Examples of activities that*
9 *violate paragraph (1) include, but are not limited to,*
10 *knowingly or intentionally—*

11 “(A) delivering, distributing, or dispensing
12 a controlled substance by means of the Internet
13 by an online pharmacy that is not validly reg-
14 istered with a modification authorizing such ac-
15 tivity as required by section 303(f) (unless ex-
16 empt from such registration);

17 “(B) writing a prescription for a controlled
18 substance for the purpose of delivery, distribu-
19 tion, or dispensation by means of the Internet in
20 violation of section 309(e);

21 “(C) serving as an agent, intermediary, or
22 other entity that causes the Internet to be used
23 to bring together a buyer and seller to engage in
24 the dispensing of a controlled substance in a

1 manner not authorized by sections 303(f) or
2 309(e);

3 “(D) offering to fill a prescription for a
4 controlled substance based solely on a consumer’s
5 completion of an online medical questionnaire;
6 and

7 “(E) making a material false, fictitious, or
8 fraudulent statement or representation in a noti-
9 fication or declaration under subsection (d) or
10 (e), respectively, of section 311.

11 “(3) INAPPLICABILITY.—

12 “(A) This subsection does not apply to—

13 “(i) the delivery, distribution, or dis-
14 pensation of controlled substances by non-
15 practitioners to the extent authorized by
16 their registration under this title;

17 “(ii) the placement on the Internet of
18 material that merely advocates the use of a
19 controlled substance or includes pricing in-
20 formation without attempting to propose or
21 facilitate an actual transaction involving a
22 controlled substance; or

23 “(iii) except as provided in subpara-
24 graph (B), any activity that is limited to—

1 “(I) the provision of a tele-
2 communications service, or of an Inter-
3 net access service or Internet informa-
4 tion location tool (as those terms are
5 defined in section 231 of the Commu-
6 nications Act of 1934); or

7 “(II) the transmission, storage, re-
8 trieval, hosting, formatting, or trans-
9 lation (or any combination thereof) of
10 a communication, without selection or
11 alteration of the content of the commu-
12 nication, except that deletion of a par-
13 ticular communication or material
14 made by another person in a manner
15 consistent with section 230(c) of the
16 Communications Act of 1934 shall not
17 constitute such selection or alteration
18 of the content of the communication.

19 “(B) The exceptions under subclauses (I)
20 and (II) of subparagraph (A)(iii) shall not
21 apply to a person acting in concert with a per-
22 son who violates paragraph (1).

23 “(4) KNOWING OR INTENTIONAL VIOLATION.—
24 Any person who knowingly or intentionally violates

1 *this subsection shall be sentenced in accordance with*
2 *subsection (b).”.*

3 (g) *PUBLICATION.*—Section 403(c) of the Controlled
4 *Substances Act (21 U.S.C. 843(c)) is amended by—*

5 (1) *striking “(c)” and inserting “(c)(1)”;* and

6 (2) *adding at the end the following:*

7 “(2)(A) *It shall be unlawful for any person to know-*
8 *ingly or intentionally use the Internet, or cause the Internet*
9 *to be used, to advertise the sale of, or to offer to sell, dis-*
10 *tribute, or dispense, a controlled substance where such sale,*
11 *distribution, or dispensing is not authorized by this title*
12 *or by the Controlled Substances Import and Export Act.*

13 “(B) *Examples of activities that violate subparagraph*
14 *(A) include, but are not limited to, knowingly or inten-*
15 *tionally causing the placement on the Internet of an adver-*
16 *tisement that refers to or directs prospective buyers to Inter-*
17 *net sellers of controlled substances who are not registered*
18 *with a modification under section 303(f).*

19 “(C) *Subparagraph (A) does not apply to material*
20 *that either—*

21 “(i) *merely advertises the distribution of con-*
22 *trolled substances by nonpractitioners to the extent*
23 *authorized by their registration under this title; or*

24 “(ii) *merely advocates the use of a controlled*
25 *substance or includes pricing information without at-*

1 *tempting to facilitate an actual transaction involving*
 2 *a controlled substance.”.*

3 (h) *INJUNCTIVE RELIEF.*—Section 512 of the Con-
 4 *trolled Substances Act (21 U.S.C. 882) is amended by add-*
 5 *ing at the end the following:*

6 “(c) *STATE CAUSE OF ACTION PERTAINING TO ONLINE*
 7 *PHARMACIES.*—

8 “(1) *IN GENERAL.*—In any case in which the
 9 State has reason to believe that an interest of the resi-
 10 dents of that State has been or is being threatened or
 11 adversely affected by the action of a person, entity, or
 12 Internet site that violates the provisions of section
 13 303(f), 309(e), or 311, the State may bring a civil ac-
 14 tion on behalf of such residents in a district court of
 15 the United States with appropriate jurisdiction—

16 “(A) to enjoin the conduct which violates
 17 this section;

18 “(B) to enforce compliance with this section;

19 “(C) to obtain damages, restitution, or other
 20 compensation, including civil penalties under
 21 section 402(b); and

22 “(D) to obtain such other legal or equitable
 23 relief as the court may find appropriate.

24 “(2) *SERVICE; INTERVENTION.*—

1 “(A) Prior to filing a complaint under
2 paragraph (1), the State shall serve a copy of the
3 complaint upon the Attorney General and upon
4 the United States Attorney for the judicial dis-
5 trict in which the complaint is to be filed. In
6 any case where such prior service is not feasible,
7 the State shall serve the complaint on the Attor-
8 ney General and the appropriate United States
9 Attorney on the same day that the State’s com-
10 plaint is filed in Federal district court of the
11 United States. Such proceedings shall be inde-
12 pendent of, and not in lieu of, criminal prosecu-
13 tions or any other proceedings under this title or
14 any other laws of the United States.

15 “(B) Upon receiving notice respecting a
16 civil action pursuant to this section, the United
17 States shall have the right to intervene in such
18 action and, upon so intervening, to be heard on
19 all matters arising therein, and to file petitions
20 for appeal.

21 “(C) Service of a State’s complaint on the
22 United States as required in this paragraph
23 shall be made in accord with the requirements of
24 rule 4(i)(1) of the Federal Rule of Civil Proce-
25 dure.

1 “(3) *POWERS CONFERRED BY STATE LAW.*—For
2 *purposes of bringing any civil action under para-*
3 *graph (1), nothing in this Act shall prevent an attor-*
4 *ney general of a State from exercising the powers con-*
5 *ferred on the attorney general of a State by the laws*
6 *of such State to conduct investigations or to admin-*
7 *ister oaths or affirmations or to compel the attend-*
8 *ance of witnesses of or the production of documentary*
9 *or other evidence.*

10 “(4) *VENUE.*—Any civil action brought under
11 *paragraph (1) in a district court of the United States*
12 *may be brought in the district in which the defendant*
13 *is found, is an inhabitant, or transacts business or*
14 *wherever venue is proper under section 1391 of title*
15 *28, United States Code. Process in such action may*
16 *be served in any district in which the defendant is an*
17 *inhabitant or in which the defendant may be found.*

18 “(5) *NO PRIVATE RIGHT OF ACTION.*—No private
19 *right of action is created under this subsection.*

20 “(6) *LIMITATION.*—No civil action may be
21 *brought under paragraph (1) against—*

22 “(A) *the United States;*

23 “(B) *an Indian Tribe or tribal organiza-*
24 *tion, to the extent such tribe or tribal organiza-*
25 *tion is lawfully carrying out a contract or com-*

1 *pact under the Indian Self-Determination and*
 2 *Education Assistance Act; or*

3 “(C) *any employee of the United States or*
 4 *such Indian tribe or tribal organization, pro-*
 5 *vided such agent or employee is acting in the*
 6 *usual course of business or employment, and*
 7 *within the scope of the official duties of such*
 8 *agent or employee therewith.”.*

9 (i) *IMPORT AND EXPORT ACT.*—Section 1010(b) of the
 10 *Controlled Substances Import and Export Act (21 U.S.C.*
 11 *960(b)) is amended—*

12 (1) *in paragraph (4)—*

13 (A) *by striking “or any quantity of a con-*
 14 *trolled substance in schedule III, IV, or V, (ex-*
 15 *cept a violation involving flunitrazepam and ex-*
 16 *cept a violation involving gamma hydroxy-*
 17 *butyric acid)”;*

18 (B) *by inserting “or” before “less than one*
 19 *kilogram of hashish oil”;* and

20 (C) *by striking “imprisoned” and all that*
 21 *follows through the end of the paragraph and in-*
 22 *serting “sentenced in accordance with section*
 23 *401(b)(1)(D).”;*

24 (2) *by adding at the end the following:*

1 “(5) *In the case of a violation of subsection (a) involv-*
 2 *ing a controlled substance in schedule III, such person shall*
 3 *be sentenced in accordance with section 401(b)(1).*

4 “(6) *In the case of a violation of subsection (a) involv-*
 5 *ing a controlled substance in schedule IV, such person shall*
 6 *be sentenced in accordance with section 401(b)(2).*

7 “(7) *In the case of a violation of subsection (a) involv-*
 8 *ing a controlled substance in schedule V, such person shall*
 9 *be sentenced in accordance with section 401(b)(3).”; and*

10 *(3) in paragraph (3), by striking “, nor shall a*
 11 *person so sentenced be eligible for parole during the*
 12 *term of such a sentence” in the final sentence.*

13 *(j) EFFECTIVE DATE.—*

14 *(1) IN GENERAL.—Except as provided in para-*
 15 *graph (2), the amendments made by this Act shall*
 16 *take effect 180 days after the date of enactment of this*
 17 *Act.*

18 *(2) DEFINITION OF PRACTICE OF TELEMEDI-*
 19 *CINE.—*

20 *(A) IN GENERAL.—Until the earlier of 3*
 21 *months after the date on which regulations are*
 22 *promulgated to carry out section 311(h) of the*
 23 *Controlled Substances Act, as amended by this*
 24 *Act, or 15 months after the date of enactment of*
 25 *this Act—*

1 (i) the definition of the term “practice
2 of telemedicine” in subparagraph (B) of
3 this paragraph shall apply for purposes of
4 the Controlled Substances Act; and

5 (ii) the definition of the term “practice
6 of telemedicine” in section 102(54) of the
7 Controlled Substances Act, as amended by
8 this Act, shall not apply.

9 (B) *TEMPORARY PHASE-IN OF TELEMEDI-*
10 *CINE REGULATION.*—During the period specified
11 in subparagraph (A), the term “practice of tele-
12 medicine” means the practice of medicine in ac-
13 cordance with applicable Federal and State laws
14 by a practitioner (as that term is defined in sec-
15 tion 102 of the Controlled Substances Act (21
16 U.S.C. 802)) (other than a pharmacist) who is
17 at a location remote from the patient and is
18 communicating with the patient, or health care
19 professional who is treating the patient, using a
20 telecommunications system referred to in section
21 1834(m) of the Social Security Act (42 U.S.C.
22 1395m(m)), if the practitioner is using an inter-
23 active telecommunications system that satisfies
24 the requirements of section 410.78(a)(3) of title
25 42, Code of Federal Regulations.

1 (C) *RULE OF CONSTRUCTION.*—*Nothing in*
 2 *this subsection may be construed to create a*
 3 *precedent that any specific course of conduct*
 4 *constitutes the “practice of telemedicine” (as that*
 5 *term is defined in section 102(54) of the Con-*
 6 *trolled Substances Act, as amended by this Act)*
 7 *after the end of the period specified in subpara-*
 8 *graph (A).*

9 (k) *GUIDELINES AND REGULATIONS.*—

10 (1) *IN GENERAL.*—*The Attorney General may*
 11 *promulgate and enforce any rules, regulations, and*
 12 *procedures which may be necessary and appropriate*
 13 *for the efficient execution of functions under this Act*
 14 *or the amendments made by this Act, and, with the*
 15 *concurrence of the Secretary of Health and Human*
 16 *Services where this Act or the amendments made by*
 17 *this Act so provide, promulgate any interim rules*
 18 *necessary for the implementation of this Act or the*
 19 *amendments made by this Act, prior to its effective*
 20 *date.*

21 (2) *SENTENCING GUIDELINES.*—*The United*
 22 *States Sentencing Commission, in determining wheth-*
 23 *er to amend, or establish new, guidelines or policy*
 24 *statements, to conform the Federal sentencing guide-*
 25 *lines and policy statements to this Act and the*

1 *amendments made by this Act, should not construe*
2 *any change in the maximum penalty for a violation*
3 *involving a controlled substance in a particular*
4 *schedule as being the sole reason to amend, or estab-*
5 *lish a new, guideline or policy statement.*

6 *(l) ANNUAL REPORT.—Not later than 180 days after*
7 *the date of enactment of this Act, and annually for 2 years*
8 *after the initial report, the Drug Enforcement Administra-*
9 *tion, in consultation with the Department of State, shall*
10 *submit to Congress a report describing—*

11 *(1) the foreign supply chains and sources of con-*
12 *trolled substances offered for sale without a valid pre-*
13 *scription on the Internet;*

14 *(2) the efforts and strategy of the Drug Enforce-*
15 *ment Administration to decrease the foreign supply*
16 *chain and sources of controlled substances offered for*
17 *sale without a valid prescription on the Internet; and*

18 *(3) the efforts of the Drug Enforcement Adminis-*
19 *tration to work with domestic and multinational*
20 *pharmaceutical companies and others to build inter-*
21 *national cooperation and a commitment to fight on*
22 *a global scale the problem of distribution of controlled*
23 *substances over the Internet without a valid prescrip-*
24 *tion.*

1 **SEC. 4. RULE OF CONSTRUCTION.**

2 *Nothing in this Act or the amendments made by this*
3 *Act shall be construed as authorizing, prohibiting, or lim-*
4 *iting the use of electronic prescriptions for controlled sub-*
5 *stances.*

Union Calendar No. 565

110TH CONGRESS
2D Session

H. R. 6353

[Report No. 110-869, Part I]

A BILL

To amend the Controlled Substances Act to address
online pharmacies.

SEPTEMBER 23, 2008

Committee on the Judiciary discharged; committed to the
Committee of the Whole House on the State of the
Union and ordered to be printed